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# FreeStyle

## InsuLinx

Blood Glucose Monitoring System



**Owner's Booklet**

## FreeStyle InsuLinX at a Glance

### Touch screen

Displays your test results and other important information. Use touch screen buttons to work with your meter.

### USB port

Plug in your micro USB cable here to download test results.

### Test strip port and light

Insert a test strip here. The meter powers on when you insert a test strip.

### Meter Home button

This button is used to turn the meter on and off, control the backlight and to go back to the Home screen.

### Test strip

Insert strip into the meter with printed side up.

### Sample areas

Apply blood or control solution to one sample area only.





















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## Symbols

| Symbol  | What It Means                                    | Symbol  | What It Means   |
|---|--|---|---|
|  | Settings   |  | Meter out of temperature range  |
|  | Extras   |  | View blood glucose results in chart form when weekly messages option is turned on |
|  | Strip light on/off switch                        |  | Drop down menu for sorting results in logbook chart view                          |
|  | Reminders  |  | Meal marker: Before meal result   |
|  | Logbook  |  | Meal marker: After meal result  |
|  | Insulin marker                                   |  | Meal marker: Other time/no mark   |
|  | Estimated rapid-acting insulin remaining in body |  | Indicates a control solution test result  |
|  | Weekly messages (not read and read)              |  | Low battery   |
|  | Insulin log feature                              |  | Caution   |

## Important Information About Your Blood Glucose Monitoring System

### CAUTION:

- Please read all the instructions provided in this Owner's Booklet and practise the testing procedures before using the FreeStyle InsuLinX system. Before setting up and using your meter, work with your health care professional to determine which meter features are most appropriate for you and your diabetes management.
- The meter and its accessories are for use by a single person. They must not be used on more than one person including other family members due to the risk of spreading infection. All parts of the meter and its accessories are considered biohazardous and can potentially transmit infectious diseases, even after performing the cleaning procedure.<sup>1,2</sup>

**WARNING:** This system contains small parts that may be dangerous if swallowed.

When removing your new FreeStyle InsuLinX system from its packaging, check that the contents are undamaged and that you have all parts listed on the box. If any parts are missing or damaged, contact Customer Service.

## Intended Use


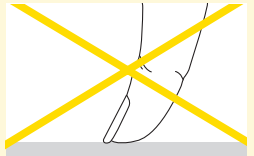
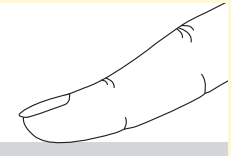

Use outside the body only (*in vitro* diagnostic use).

The FreeStyle InsuLinx Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in capillary whole blood from the finger, hand, forearm, upper arm and venous whole blood. It is intended for use by people with diabetes mellitus for self-testing and by health care professionals as an aid in monitoring the effectiveness of diabetes control programs. It provides the user with electronic logbook functions that store data such as insulin and medication doses, food intake, amount of exercise and health information. The meter includes a data port and on-board software that enables the user to download electronic data to a personal computer. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates or with arterial blood.

Additionally, the FreeStyle InsuLinx Blood Glucose Monitoring System is intended for use in home and clinical settings to aid people with diabetes and health care professionals in the review, analysis and evaluation of historical blood glucose test results to support an effective diabetes management program. The system may also aid in the management of diabetes by calculating a suggested insulin dose based on user entered data.

## Set up Your Meter for the First Time

Set the language, current date and time.

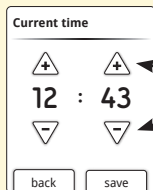
| Step | Action  |
|------|---|
| 1    |  Press the meter Home button.  |
| 2    | <div></div> <p>Tap the language you want the meter to use.</p> <p>Use the pad of your finger. Do not use your fingernail or any other object to tap the screen</p> <p><b>Note:</b> The <b>OK</b> button will appear when you select the language. Tap the <b>OK</b> button to move to the next screen.</p> |

3



Tap the **arrow buttons** to change the date. Then tap **save**.

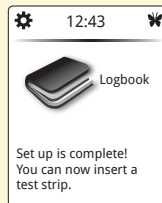
4



Tap the **arrow buttons** to set the time. Then tap **save**.

#### Notes:

- You will see the Home screen when you complete this step.



- If you don't complete these steps, the meter will continue to prompt you to set the language when you turn it on.

**IMPORTANT:** If the date and time are not set correctly, some meter functions may not work correctly. If the time setting is lost, the time display flashes --:-- until it is reset.

## Getting to Know Your Meter

Learn how to turn your meter on and off, find the Home screen, use the ? Help button, and use the backlight and strip light.

### Turn Your Meter On and Off



To turn the meter on:

- Press the meter Home button, or
- Insert a test strip.

To turn the meter off:

- If you're on the home screen, press the meter Home button, or
- Remove a test strip, or
- Do nothing for **2 minutes**.

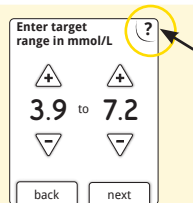
### Find the Home Screen



Most of your meter activities will begin at the Home screen.

Press the meter Home button anytime to return to the Home screen **except** when a test strip is inserted.

## Use the “?” Help Button



Tap the ? Help button anytime you see it and want more information.

## Turn the Backlight On and Off

The backlight can help you view the screen in low light.

To turn the backlight on:

- Press and hold the meter Home button for **3 seconds**.


To turn the backlight off:

- Wait for 15 seconds, or
- Press and hold the meter Home button for **3 seconds**.


## Turn the Strip Light On and Off



To turn the strip light on:

- If a test strip is inserted, press and hold the meter Home button for **3 seconds**.
- If a test strip is not inserted, turn the backlight on, then tap the strip light symbol  on the home screen.

To turn the strip light off:

- Tap the strip light symbol .

## Test Your Blood Glucose

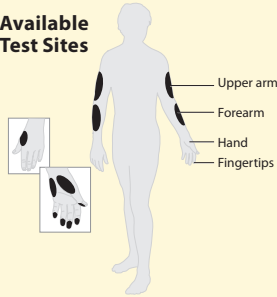


Get a blood glucose test result.

You will need:

- FreeStyle Lite test strips that are not expired.
- Lancing device and new lancets to obtain a blood sample.

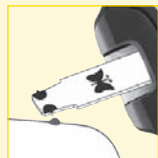
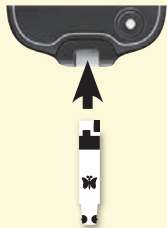
### IMPORTANT:

- Use only FreeStyle Lite test strips. Only use a test strip once.
- Read the test strip insert before performing your first blood glucose test. It contains important information and will tell you how to store and handle the test strips.
- The meter and its accessories are for use by a single person. They must not be used on more than one person including other family members due to the risk of spreading infection. All parts of the meter and its accessories are considered biohazardous and can potentially transmit infectious diseases, even after performing the cleaning procedure.<sup>1,2</sup>
- Do not re-use lancets due to risk of infection. Not suitable for re-sterilisation.
- Bruising may occur at the test site. If bruising occurs, consider selecting another site.
- Refer to the lancing device insert for detailed instructions on how to use the FreeStyle lancing device.

| Step | Action  |
|------|---|
| 1    | <p>Select your test site.</p> <p><b>Available Test Sites</b></p>  <p><b>Note:</b> Avoid moles, veins, bones, and tendons. Bruising may occur at the test site. If bruising occurs, consider selecting another site.</p> <p><b>WARNING:</b> If you think you're low (hypoglycaemia) or you suffer from hypoglycaemia unawareness, test on your fingers.</p> |
| 2    |  <p>Wash your hands and the test site with soap and warm water. Rinse and dry thoroughly.</p> <ul style="list-style-type: none"> <li>• Do <b>not</b> use lotion or cream on the test site.</li> </ul>  |
| 3    |  <p>Check the test strip expiry date.</p> <ul style="list-style-type: none"> <li>• Do <b>not</b> use expired test strips; they may cause inaccurate results.</li> </ul>  |



4



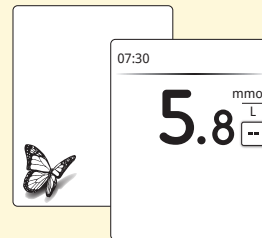
Perform the test.

- Insert a test strip and close the test strip vial.
- Use your lancing device to obtain a blood drop.
- Apply blood to the test strip as shown in the picture.
- The meter will beep once to let you know that you have applied enough blood.

**Notes:**

- Once you start applying blood, you have 60 seconds to fill the test strip on the same side of the test strip only. The time you have left is shown as a countdown on the screen.
- The time that the meter takes to display a result depends on your blood glucose level. The higher your blood glucose level, the longer it takes to get a result.
- The meter turns off after 2 minutes of inactivity. Remove and reinsert the unused test strip to restart the meter.

5



View the test result.

- A butterfly will appear on the screen while you wait for your result. The meter will beep twice when your result is ready.
- Remove and correctly discard the test strip and lancet. Contact your health care professional regarding local waste disposal requirements.

Refer to the *Your Test Results* section to learn how to understand and mark your test results.

**Note:** Your result is now stored in your logbook.

**IMPORTANT:** After performing a blood glucose test, wash your hands and the test site with soap and water. Thoroughly dry your hands and the test site.

## Your Test Results



View, understand, and mark your test results; know what to do if you receive an error message.

**Note:** The meter displays results in mmol/L. This unit of measure is set and cannot be changed.

### IMPORTANT:

- The meter displays results from 1.1 mmol/L to 27.8 mmol/L. Low or high blood glucose results can indicate a potentially serious medical condition. Contact your health care professional before taking any action based on an unclear message or result.
- The expected normal fasting blood glucose level for an adult without diabetes is less than 6.1 mmol/L.<sup>3</sup>
- Two hours after meals, the blood glucose level for an adult without diabetes should be less than 7.8 mmol/L.<sup>3</sup>
- Consult your health care professional to determine the blood glucose levels that are appropriate for you.
- Consult your health care professional before changing your diabetes management program.

## Low and High Blood Glucose Results

| Display   | What To Do   |
|---|--|
| <div> <b>Low glucose</b></div> <p>Appears when result is:<br/>lower than<br/>3.9 mmol/L</p>    | Follow your health care professional's advice to treat low blood glucose.  |
| <div> <b>High glucose</b></div> <p>Appears when result is:<br/>higher than<br/>13.3 mmol/L</p> | Follow your health care professional's advice to treat high blood glucose. |

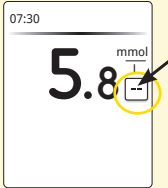
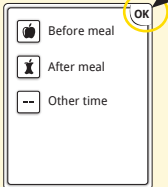
| Display   | What To Do  |
|---|---|
| <p><b>LO</b></p> <p>Appears when result is: lower than 1.1 mmol/L</p>   | <ol style="list-style-type: none"> <li>1. LO may indicate that your blood glucose is very low. Follow your health care professional's advice immediately and then repeat the test.</li> <li>2. If your blood glucose results do not match how you feel, perform a control solution test to confirm that your meter and strips are working correctly.</li> </ol>   |
| <p><b>HI</b></p> <p>Appears when result is: higher than 27.8 mmol/L</p> | <ol style="list-style-type: none"> <li>1. HI may indicate that your blood glucose is very high. Wash your hands or the alternative test site and then repeat the test. If the result is HI again, follow your health care professional's advice immediately.</li> <li>2. If your blood glucose results do not match how you feel, perform a control solution test to confirm that your meter and strips are working correctly.</li> </ol> |

#### IMPORTANT:

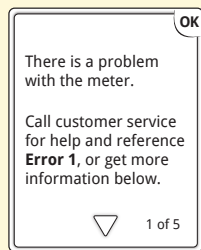
- Severe dehydration may cause false low results. If you believe you are suffering from severe dehydration, contact your health care professional immediately.
- Contact your health care professional if you have symptoms that do **not** match your test result, and you have followed the instructions in this Owner's Booklet.

## Use Meal Markers

Mark your blood glucose test result as 'Before meal' or 'After meal', or as another time. Meal markers are used to provide additional information for Weekly Messages and in the FreeStyle Auto-Assist reports.

| Step | Action   |
|------|--|
| 1    | <p>When viewing your blood glucose test result, tap the <b>dashes —</b>.</p>    |
| 2    | <p>Tap your selection. Tap <b>OK</b> to return to the result screen.</p> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>• If you mark as <b>Before meal</b>, you can choose to set a test reminder for 1 or 2 hours after your meal.</li> <li>• You can select <b>Other time</b> if you are testing at times other than before or after a meal.</li> <li>• If you need to, you can change a meal marker for the current result by tapping the meal marker button from the result screen.</li> </ul>  |

## Error Messages



Example of an Error Message

Your meter will explain what an error message means, its possible causes, and what to do about it.

### Notes:

- Remember to tap the arrow button to see all of the important information.
- Tap **OK** to return to the Home screen.

## Temperature Warning



This symbol may appear after inserting a test strip. It will include a message saying the meter is either too hot or too cold to use right now. Blood glucose tests taken outside of the operating temperature range may not be accurate.

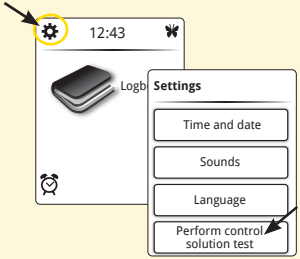

Tap **OK** to clear the screen and test again later.

## Control Solution Test

A control solution test should be performed when you are not sure of your results and want to confirm that your meter and test strips are working correctly.

### IMPORTANT:

- Control solution results should fall within the control solution range printed on the test strip vial.
- Do **not** use control solution past its expiry date. Discard control solution 3 months after opening or on the expiry date printed on the bottle, whichever comes first. (Example: open April 15, discard July 15; write the discard date on the side of the bottle.)
- The control solution range is a target range for control solution only, not for your blood glucose level.
- Use only FreeStyle control solution with this meter.
- Replace the cap securely on the bottle immediately after use.
- Do not add water or other liquid to control solution.
- There are two levels of control solution available (Low and High). Contact Customer Service for information on how to obtain control solution.

| Step | Action   |
|------|--|
| 1    | <p>At the Home screen, tap <b>Settings</b> ⚙️. Then tap <b>Perform control solution test</b>.</p>    |
| 2    | <p>Perform the control solution test.</p> <ol style="list-style-type: none"> <li>Insert a test strip and close the test strip vial.</li> <li>Apply control solution to the test strip as shown in the picture.</li> <li>The meter will beep once to let you know that you have applied enough control solution.</li> <li>A butterfly will appear on the screen while you wait for the result. The meter will beep twice when the result is ready.</li> </ol>  |

3

Compare the control solution result to the range printed on the test strip vial. The result should fall within the range.

**Notes:**



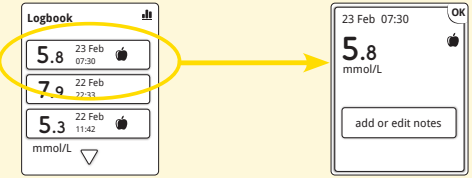
- If you see an error message on the screen, your meter will explain what it means, its possible causes, and what to do next.
- The result will be marked as a control solution test in your logbook. It will **not** be included in your charts and reports.
- You may also mark a control solution test after it is performed by following these steps:
  - At the Home screen, tap **Logbook** 📖.
  - Tap your most recent test. You can only modify this result.
  - Tap the down arrow. Then tap **add or edit notes**.
  - Tap the option for **control solution test**. Then tap **OK**.
  - You can now see your most recent result marked as a control solution test.
- Do **not** use the insulin calculator when you perform a control solution test.

Out of Range Control Solution Results

- Repeat the test if control solution results are outside the range printed on the test strip vial.
- Stop using the meter if control solution results are consistently outside the range printed on the test strip vial. Contact Customer Service.

## View Logbook

Review blood glucose history; review and log meals, insulin doses, notes about your test results and control solution tests.



| Step | Action  |
|------|---|
| 1    |  At the Home screen, tap <b>Logbook</b>  .  |
| 2    | <p>Review your results.</p> <p><b>Notes:</b></p> <ul style="list-style-type: none"><li>• Use the down arrow to scroll through logbook entries.</li><li>• Tap any entry to see details of results, calculations and notes, if any.</li></ul>  |

Continued on next page

## 2

(Continued)

### Notes (Continued):

- If you turned on the Notes feature through FreeStyle Auto-Assist, you can tap the **add or edit notes** button to add or edit notes to your most recent result. Refer to the FreeStyle Auto-Assist *Set up Advanced Features for Your Meter Logbook* section for how to set up this feature.
- If you turned on the Insulin Log feature through FreeStyle Auto-Assist, you will see the  at the top left of the screen. Tap it to enter your insulin dose. Refer to the FreeStyle Auto-Assist *Set up Advanced Features for Your Meter Logbook* section for how to set up this feature.
- If you turned on Weekly Messages, you will see the chart symbol  at the top right of the screen. Tap it to review your results for up to 14 days. To learn more about weekly messages, refer to the *Set up and Use Weekly Messages* section.
- A LO result (under 1.1 mmol/L) is included in the memory as LO.
- A HI result (over 27.8 mmol/L) is included in the memory as HI.

## Change Your Meter Settings

Change time and date, sounds or language.

| Step | Action  |
|------|---|
| 1    | <p>At the Home screen, tap <b>Settings</b> ⚙️. Then tap the setting you want to change.</p> <p><b>Note:</b> Tap <b>Sounds</b> to change Notification and Button sounds.</p> <ul style="list-style-type: none"> <li>Notification sound <b>On</b>: Meter will beep when the test strip is filled, the result appears on the screen, an error occurs, and when you get a reminder.</li> <li>Button sound <b>On</b>: Meter will beep each time you tap a button.</li> </ul> |
| 2    | <p>Press the meter Home button to return to the Home screen.</p> <p><b>Note:</b> You can change your meter settings anytime by simply repeating Step 1.</p>   |

## Personalise Your Meter

Change the picture you see when you perform a blood glucose test.



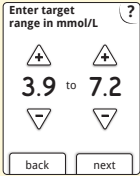
| Step | Action  |
|------|---|
| 1    | <p>At the Home screen, tap <b>Extras</b> 🦋. Then tap <b>Personalisation</b>.</p>  |
| 2    | <p>Select your picture and tap <b>yes</b> to confirm the change.</p> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>You can also use <b>my picture</b> to select a personal picture such as a family member or pet. Refer to the FreeStyle Auto-Assist <i>Set up Your Meter Personalisation</i> section for how to upload your picture.</li> <li>You can change your picture anytime by simply repeating Steps 1 and 2.</li> </ul> |

## Set up and Use Weekly Messages

Turn on and use weekly messages. This feature will help you identify patterns in your blood glucose results.

**IMPORTANT:** Ask your health care professional for your blood glucose target range.

### Set up Weekly Messages

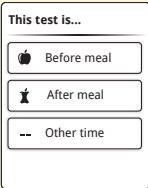



| Step | Action  |
|------|---|
| 1    |  <p>At the Home screen, tap <b>Extras</b> . Then tap <b>Weekly Messages</b>.</p>  |
| 2    |  <p>Enter your target range. This is the desired target range for blood glucose values. This target range will only be used to determine Weekly Messages. Tap <b>next</b> to save.</p> <p><b>Notes:</b></p> <ul style="list-style-type: none"><li>• Target values cannot be set below 3.9 mmol/L or above 10.0 mmol/L.</li><li>• Tap the ? Help button for more information.</li></ul> |

3

Tap **done** to return to the Home screen.

**Note:** You can change your weekly messages settings anytime by simply repeating the setup procedure.

### Use Weekly Messages

| Step | Action   |
|------|--|
| 1    | Perform a blood glucose test.  |
| 2    |  <p>Mark your meal during the blood glucose test.</p> <p>If you have set up weekly messages, you will see this screen while you wait for your blood glucose test result. Tap your selection.</p>  |
| 3    |  <p>Tap  <b>Message</b> to read weekly messages from the results screen. Then tap <b>OK</b> to get back to your blood glucose test result.</p> <p><b>Notes:</b></p> <ul style="list-style-type: none"><li>• Weekly messages will also be stored in your logbook.</li><li>•  is displayed after the message is read.</li></ul> |



## Important information about the Rapid-acting Insulin Calculator

This feature requires an understanding of the use of insulin. Misuse or misunderstanding of this feature and the suggested dose may lead to inappropriate insulin dosing. The calculator suggests doses for rapid-acting insulin only.

An access code is required to set up or change the rapid-acting insulin calculator settings. This access code is available only to your health care professional. Work with your health care professional to set up or change the calculator for you.


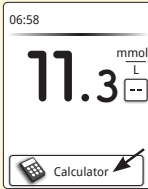
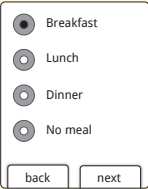
If you are unsure about your result, you can adjust the suggested dose based on instructions from your health care professional.

**CAUTION:** The rapid-acting insulin calculator is not able to account for all factors that may affect your insulin dose. These include incorrectly entered data, incorrectly set date or time, unlogged insulin, smaller or larger meals, sickness, exercise, etc. It is important that you review your suggested dose and account for these factors before taking insulin.

If you change the language on the meter after the insulin calculator is set up, the calculator will no longer be active. However, the settings are still stored on your meter and the calculator can be reactivated by your health care professional in the new language. If you return back to the original language, your calculator will remain active.

## Use Your Insulin Calculator with Easy Option

Use the Easy Option if you start with a fixed dose of rapid-acting insulin for meals.

| Step | Action  |
|------|---|
| 1    |  Test your blood glucose. We recommend that you test on your finger when using the insulin calculator.   |
| 2    |  After reviewing your result, tap the <b>Calculator</b> button.<br><b>Notes:</b> <ul style="list-style-type: none"><li>You have up to 15 minutes to access the calculator. If your meter turns off, press the meter Home button once to get back to this screen.</li><li>When your blood glucose result is below 3.3 mmol/L, the <b>Calculator</b> button will NOT appear.</li><li>Do not use control solution to obtain a suggested dose.</li></ul> |
| 3    |  Choose the meal you are about to eat. Tap <b>next</b> .   |

4

These numbers are for illustrative purposes only.

Review your suggested dose.

- If needed, tap the arrow buttons to adjust your suggested dose for any planned activity, a smaller or larger meal, sickness, etc.
- Tap the **i** button to see details of what is included in your suggested dose.

- This is the insulin dose provided by your health care professional to cover the food you are going to eat (BREAKFAST, LUNCH AND DINNER).
- This is the insulin to bring your blood glucose level within your target (CORRECTION TARGET). The meter will use your CORRECTION FACTOR to calculate the insulin required. If you do not adjust your insulin for your glucose level, this line will not appear.
- ACTIVE INSULIN: This is the logged insulin that is still active in your body and is being subtracted to give a total suggested dose.
- This is the change that **you** have made to your suggested dose to adjust for a smaller or larger meal, sickness or any planned activity, such as exercise.
- This is your total suggested dose.**

5


Tap **log dose** to save to your logbook and then take your dose. If you do not tap **log dose**, your dose will not be stored in your logbook.

**CAUTION:** It is important to log all your rapid-acting insulin doses so your meter can account for active insulin when calculating your suggested doses. Failure to log all your rapid-acting insulin doses may result in a suggested dose that is too high.

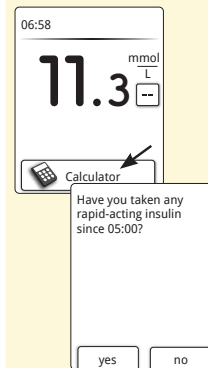
**Note:** The total dose is rounded to the nearest full unit (1.0) or half unit (0.5) depending on how your health care professional set up the calculator. Similar to conventional math rounding rules, the calculator rounds up from 0.5. The suggested dose will not exceed 50 units, the maximum allowable dose by the meter.

## Use Your Insulin Calculator with Advanced Option

Use the Advanced Option if you count carbohydrates (in grams or carbohydrate portions) to adjust your rapid-acting insulin dose for meals.

| Step | Action   |
|------|--|
| 1    |  <p>Test your blood glucose.<br/>We recommend that you test on your finger when using the insulin calculator.</p> |

2

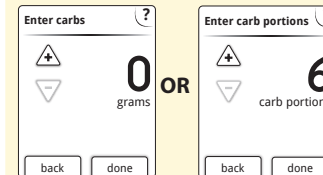


After reviewing your result, tap the **Calculator** button and confirm your last logged rapid-acting insulin dose if needed (you will be asked this if your health care professional turned on the Active Insulin feature). The time displayed in the confirmation screen will be the current time minus the insulin duration or the time of the last logged dose, whichever is most recent. This is to ensure an accurate accounting of active insulin.

### Notes:

- Rapid-acting insulin entered here will be added to the active insulin tracking.
- You have up to 15 minutes to access the calculator. If your meter turns off, press the meter Home button once to get back to this screen.
- When your blood glucose result is below 3.3 mmol/L, the **Calculator** button will NOT appear.
- Do not use control solution to obtain a suggested dose.

3



Use the arrow buttons to enter the grams of carbs or carbohydrate portions you are about to eat. Tap **done**.

Suggested dose i

Adjust if needed

+ 12 u  
- User change: +2

back log dose

Review your suggested dose.

- If needed, tap the arrow buttons to adjust your suggested dose for any planned activity, a smaller or larger meal, sickness, etc.
- Tap the i button to see details of what is included in your suggested dose.

Dose details OK

For 70 g carbs..... 9  
For 11.3 mmol/L..... + 2  
Active insulin ..... - 1  
User change..... + 2  
Total..... 12u

1 of 3

These numbers are for illustrative purposes only.

- This is the insulin to cover the food you are going to eat. The meter will use your CARBOHYDRATE RATIO or CARBOHYDRATE PORTIONS RATIO to calculate how much insulin is needed for the food you are going to eat.
- This is the insulin to bring your blood glucose level within your target (CORRECTION TARGET). The meter will use your CORRECTION FACTOR to calculate the insulin required.
- ACTIVE INSULIN: This is the logged insulin that is still active in your body and is being subtracted to give a total suggested dose. The meter will use your INSULIN DURATION and information about your last logged dose to calculate how much insulin is still active in your body.
- This is the change that **you** have made to your suggested dose to adjust for a smaller or larger meal, sickness or any planned activity, such as exercise.
- This is your total suggested dose.**

Suggested dose i

Adjust if needed

+ 12 u  
- User change: +2

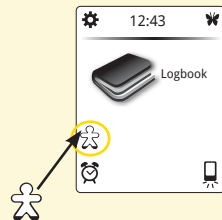
back log dose


Tap **log dose** to save to your logbook and then take your dose. If you do not tap **log dose**, your dose will not be stored in your logbook.

**CAUTION:** It is important to log all your rapid-acting insulin doses so your meter can account for active insulin when calculating your suggested doses. Failure to log all your rapid-acting insulin doses may result in a suggested dose that is too high.

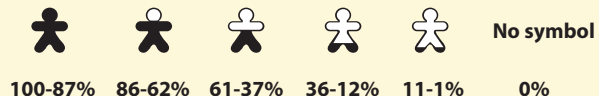
**Note:** The total dose is rounded to the nearest full unit (1.0) or half unit (0.5) depending on how your health care professional set up the calculator. Similar to conventional math rounding rules, the calculator rounds up from 0.5. The suggested dose will not exceed 50 units, the maximum allowable dose by the meter.

## Active Insulin symbol



If your health care professional turned on the Active Insulin feature, this symbol may now appear on your home screen. It shows an estimate of the amount of rapid-acting insulin still in your body and how much longer it may be active. Tap on the  symbol to see more information about the remaining rapid-acting insulin from your logged doses.



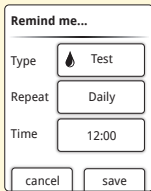
### Estimated percentage of active insulin remaining in your body

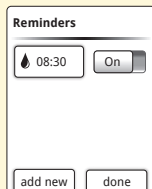


## Set up and Use Reminders

Set your meter to remind you when to test, when to take your insulin, or for other alarms.

### Set up Reminders

| Step | Action  |
|------|---|
| 1    |  <p>At the Home screen, tap the <b>Clock</b> .</p> <p>You will see the 'Remind me' screen with your menu of options.</p>  |
| 2    |  <p>a. Tap <b>Type</b> of reminder button to select which reminder you want to set (Test, Take Insulin or Alarm).</p> <p>b. Tap <b>Repeat</b> button to set how often you want the reminders (Daily, Once, Countdown Timer).</p> <p>c. Tap <b>Time</b> and tap the arrow buttons to set the reminder time.</p> <p>Tap <b>save</b>.</p> |



You can now:

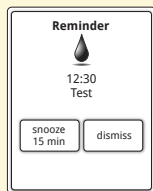
- Tap the **On/Off** button to turn a reminder on or off.
- Tap **add new** to set more reminders.

Tap **done** to return to the Home screen. When any reminders are turned On, the time of your next reminder will appear on your home screen next to the ⌚.

**Notes:**

- You can change your reminders anytime by simply repeating the setup procedure.
- To add a reminder such as when to exercise, refer to the FreeStyle Auto-Assist *Set up Meter Reminders* section.

## Use Reminders



Your reminder will appear even if the meter is turned off.

Tap your selection to **snooze** or **dismiss** your reminder.

**Notes:**

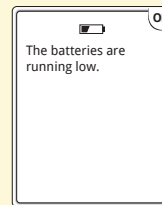
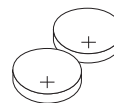
- Missed reminders will remain on the screen until dismissed.
- If you have set an insulin reminder and have turned on the Insulin Log feature through FreeStyle Auto-Assist, you will be able to log a dose after tapping **dismiss** when the reminder appears. If you enter a rapid-acting insulin dose here, it will be stored as “meal” insulin when you print reports through FreeStyle Auto-Assist.

## Taking Care of Your Meter

Take care of your meter and keep it operating safely.

### Changing Batteries

**Note:** The meter uses **2** replaceable CR 2032 coin cell batteries.

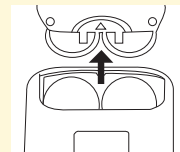


You will see this screen when your batteries are low.

**Note:** Your meter settings and logbook information will be saved when you change the batteries.

**IMPORTANT:** After you first see this warning, you can perform approximately 28 tests before you need to change the batteries.

| Step | Action   |
|------|--|
| 1    | <p>Change your batteries.</p> <ol style="list-style-type: none"> <li>Slide open the battery door on the back of the meter.</li> <li>Remove the old batteries.</li> <li>Install new batteries with (+) facing up.</li> <li>Slide the door back into place until it clicks.</li> </ol> <p><b>Note:</b> The next time you turn your meter on, it will ask you to confirm the time and date.</p> |




*The batteries in this product should be removed and disposed of in accordance with local regulations for separate collection of spent batteries.*

## Cleaning Your Meter

| Step | Action  |
|------|---|
| 1    | Assemble cleaning supplies: <ul style="list-style-type: none"> <li>• Cloth dampened with:</li> <li>• Mild detergent/soap and water, or</li> <li>• 70% isopropyl alcohol, or</li> <li>• A mixture of 1 part household bleach, 9 parts water</li> </ul>                       |
| 2    | <div> <b>IMPORTANT:</b> Do <b>not</b> place the meter in water or other liquids. Avoid getting dust, dirt, blood, control solution, water or any other substance in the meter's test strip port and USB port.         </div> <p>Gently clean the exterior of the meter.</p> |
| 3    | Allow the meter to dry.   |

## Troubleshooting

|  | What It Means   | What To Do  |
|--|---|---|
| 1. Test strip is inserted in the port and nothing happens. | <ul style="list-style-type: none"> <li>• Test strip is inserted incorrectly or not fully inserted into the meter</li> </ul>           | Insert the test strip as shown.  |
|  | <ul style="list-style-type: none"> <li>• No batteries are installed</li> <li>• Batteries are installed incorrectly</li> </ul>         | Install batteries with (+) facing up.   |
|  | <ul style="list-style-type: none"> <li>• Dead batteries</li> </ul>  | 1. Change batteries. Reset date and time, if needed.<br>2. If problem continues, contact Customer Service.          |
|  | <ul style="list-style-type: none"> <li>• Meter may be plugged into a computer</li> </ul>  | Unplug the meter from the computer.   |
|  | <ul style="list-style-type: none"> <li>• Problem with test strip</li> </ul>   | Try a new test strip.   |
|  | <ul style="list-style-type: none"> <li>• Problem with meter</li> <li>• Blood or foreign objects put in the test strip port</li> </ul> | Contact Customer Service.   |
|  |   |   |

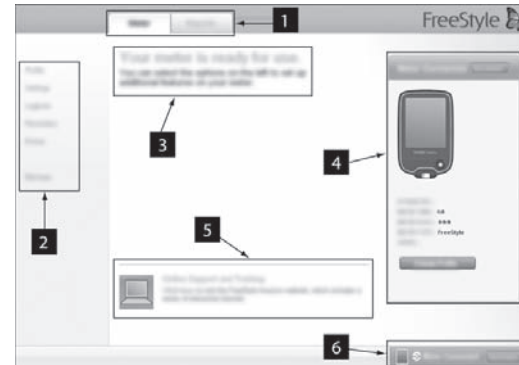
|   | What It Means   | What To Do  |
|---|---|---|
| 2. The test does not start after applying the blood drop. | <ul style="list-style-type: none"> <li>Blood drop is too small</li> </ul>   | Add blood to the same sample area within 60 seconds, or repeat the test using a new test strip and a larger blood drop.   |
|   | <ul style="list-style-type: none"> <li>Problem with test strip</li> <li>Sample applied after meter turns off</li> </ul> | <ol style="list-style-type: none"> <li>Repeat the test using a new test strip. Wait for 'apply blood to strip' message to appear before applying blood (or 'apply control solution to strip' message if you are applying control solution).</li> <li>If problem continues, contact Customer Service.</li> </ol> |
|   | <ul style="list-style-type: none"> <li>Problem with meter</li> </ul>  | Contact Customer Service.   |

## FreeStyle Auto-Assist: Progress Reporting Software

### Getting to Know Your FreeStyle Auto-Assist Software

Welcome to FreeStyle Auto-Assist. This software tool allows you to take a more informed role in managing your diabetes. It can help you and your health care professional evaluate needs and options for your diabetes management program.

**Note:** Your meter must be connected to the computer in order to modify settings or view reports. Reports will be created based on the current data saved on your meter. No data from the meter logbook is saved to your computer.



- Meter and Report tabs:** Provide access to meter setup features or report options.
- Submenu:** Provides access to additional features within each tab.
- Message box:** Keeps you posted on software status and any next steps (if needed).
- Meter information:** Shows meter details such as time, date, serial number and patient name/ID.

- Online Support and Training:** Provides a link to online training and support.
- Meter Status Bar:** Displays meter connection status.



## Install the FreeStyle Auto-Assist Software

**Note:** FreeStyle Auto-Assist is compatible with both PC and Mac operating systems.

| Step | Action   |
|------|--|
| 1    | With your meter off, use the provided micro USB cable to connect your meter's USB port to your computer. If you do not have the micro USB cable provided with the meter, you may use other micro USB cables. |
| 2    | The software will start automatically for installation or use. Follow the InstallShield Wizard prompts. Click <b>Next</b> after each entry. Note that you may be asked to supply an administrator password.  |
| 3    | Click <b>Finish</b> or <b>Close</b> once installation is complete. The program will automatically launch whenever you connect the meter to your computer.  |

**WARNING:** To avoid the possibility of electric shock, never perform a blood glucose test while the meter is connected to the computer.

If the installation does not automatically start, follow the steps below to install the software.

### Windows Computer Systems (includes Windows 7, Windows Vista and Windows XP)

| Step | Action  |
|------|---|
| 1    | Locate "My Computer" on your desktop. Double-click "My Computer" to open.                 |
| 2    | Locate the "FreeStyle Auto-Assist" icon. Double-click on this icon to open.               |
| 3    | Locate the "Windows" folder. Double-click on this folder to open.                         |
| 4    | Locate the "Disk1" folder. Double-click on this folder to open.                           |
| 5    | Locate the "Setup application" icon. Double-click on this icon to begin the installation. |

### Macintosh Computer Systems (OS X, includes Leopard, Snow Leopard and Lion)

| Step | Action   |
|------|--|
| 1    | In the Finder window, select the Device called "FreeStyle Auto-Assist" in the Devices section. |
| 2    | Within the FreeStyle Auto-Assist Device, select "Mac".   |
| 3    | Double-click on the "FreeStyle Auto-Assist.pkg" file.  |

For additional questions, please contact Customer Service.

## FreeStyle Auto-Assist System Requirements

- At minimum, a computer with a USB 2.0 compliant hub running Windows with a single-core 1GHz processor and 512MB RAM or running Mac OS X Leopard with an Intel dual-core 1.83GHz processor and 512MB RAM.
- Compatible operating systems:
  - Windows 7 (32 and 64 bit)
  - Windows Vista (32 and 64 bit)
  - Windows XP (Service Pack 3)
  - Macintosh Leopard, Snow Leopard and Lion (Intel processor)

## Change Your Meter Settings

Change clock style, language or sound preferences.

| Step | Action   |
|------|--|
| 1    | Go to the <b>Meter</b> tab. On the left side of the screen, click <b>Settings</b> .  |
| 2    | Make your selections: <ul style="list-style-type: none"><li>a. <b>Clock style</b>, click your choice.</li><li>b. <b>Language</b>, select your choice.</li><li>c. <b>Sound</b>, click On or Off to change your Notification or Button sounds.</li></ul> |
| 3    | Click <b>Save to meter</b> .   |

## Set up Advanced Features for Your Meter Logbook



Turn on additional meter logbook features such as the ability to log all your insulin doses and add up to 11 custom notes that can be logged with your blood glucose test results.

## Set up the Insulin Log Feature

| Step | Action   |
|------|--|
| 1    | Go to the <b>Meter</b> tab. On the left side of the screen, click <b>Logbook</b> .   |
| 2    | Make your selections: <ul style="list-style-type: none"><li>a. Click the button to <b>On</b> to record your insulin doses.</li><li>b. Check the appropriate boxes for the types of insulin you take.</li></ul> |
| 3    | Click <b>Save to meter</b> .<br><br>For more information about adding insulin doses to your meter logbook, refer to the <i>View Logbook</i> section.   |


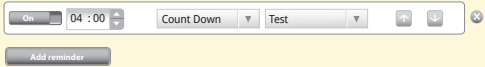
**Note:** Any rapid-acting insulin logged in the logbook will be used in the calculator's suggested insulin dose. You should always log your doses at the same time you take them in order for the calculator to suggest appropriate future doses.

## Set up Notes for Your Meter Logbook

| Step | Action  |
|------|---|
| 1    | Go to the <b>Meter</b> tab. On the left side of the screen, click <b>Logbook</b> .  |
| 2    | Click <b>Notes</b> on the Logbook submenu.  |
| 3    | <p>Make your selections:</p> <ol style="list-style-type: none"> <li>Click the button to <b>On</b> to use Notes.</li> <li>The first four notes are: Exercise, Felt ill, Medication and Felt low. You can choose to accept these; or</li> <li>Edit, change order, delete or add up to 11 custom notes. <ul style="list-style-type: none"> <li>Click <b>Edit note</b> to change the name of a note. Then click <b>Done</b>.</li> <li>Change the order of the notes by using the up and down arrows (this will change the order they appear on the meter).</li> <li>Click the  button next to the note you want to delete.</li> <li>Click <b>Add note</b> to add a custom note.</li> </ul> </li> </ol>  |
| 4    | <p>Click <b>Save to meter</b>.</p> <p>For more information about adding notes to results in your meter logbook, refer to the <i>View Logbook</i> section.</p>   |


## Set up Meter Reminders

Set your meter to remind you when to test, when to take your insulin, or for other alarms. The software allows you to set up to 12 different personal reminders.

| Step | Action  |
|------|---|
| 1    | Go to the <b>Meter</b> tab. On the left side of the screen, click <b>Reminders</b> .  |
| 2    | Set up to 12 reminders by clicking <b>Add reminder</b> .  |
| 3    | <p>Set up your reminders:</p> <ol style="list-style-type: none"> <li>Click the <b>On/Off</b> button to turn a reminder On or Off.</li> <li>Use the up and down arrows to select the time.</li> <li>Use the drop down menus to select when you want the reminder repeated and the type of reminder. You can also add a custom type of reminder.</li> <li>Click <b>Add</b> to add the reminder.</li> <li>Change the order of the reminders by using the up and down arrows (this will change the order they appear on the meter).</li> <li>Click the  button next to the reminder you want to delete.</li> </ol>  |
| 4    | <p>Click <b>Save to meter</b>.</p> <p>For more information about reminders on your meter, refer to the <i>Set up and Use Reminders</i> section.</p>   |

## Set up Your Meter Personalisation

Change the picture you see when you perform a blood glucose test.

| Step | Action   |
|------|--|
| 1    | Go to the <b>Meter</b> tab. On the left side of the screen, click <b>Extras</b> .  |
| 2    | Make your selection: <ul style="list-style-type: none"><li>Click on one of the available pictures to select it. Click <b>Save to meter</b>. You will now see this picture each time you perform a blood glucose test.</li><li>If you would like to use a personal picture from your computer, go to Step 3.</li></ul>  |
| 3    | Click <b>My Picture</b> .  |
| 4    | <p>Upload a personal picture from your computer.</p> <p>a. Click <b>Choose</b>.</p> <p>b. Select your picture. Click <b>Open</b>.</p> <p>c. Adjust your picture so that it fits inside the borders of the box.<br/>To change the size, use the slider bar.</p>  <p>d. Click <b>Set Picture</b>.</p> <p>e. Click <b>Save to meter</b>.</p> <p>For more information about personalising your meter, refer to the <i>Personalise Your Meter</i> section.</p> |



Example  
personal picture

## Set up Weekly Messages on Your Meter


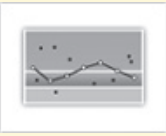

Turn on weekly messages. This feature will help you identify patterns in your blood glucose results.




**IMPORTANT:** Ask your health care professional for your blood glucose target ranges.

| Step | Action  |
|------|---|
| 1    | Go to the <b>Meter</b> tab. On the left side of the screen, click <b>Extras</b> .   |
| 2    | Turn on Weekly Messages. <ul style="list-style-type: none"><li>a. Click <b>Weekly Messages</b>.</li><li>b. Click the button to <b>On</b> to use this feature.</li><li>c. Enter your target range.</li></ul> |
| 3    | Click <b>Save to meter</b> .<br>For more information about weekly messages on your meter, refer to the <i>Set up and Use Weekly Messages</i> section.   |

# FreeStyle Auto-Assist Reports

The FreeStyle Auto-Assist software allows you to choose from six reports:

| Report  | What It Does  |
|---|---|
|  | <b>The Snapshot report</b> is a general summary of data for the specified date range. It also includes notes that inform you and your health care professional about important trends in blood glucose data by putting the data into words. Up to six notes will be displayed at one time, in order of clinical significance. |
|  | <b>The Modal Day Report</b> shows the daily pattern of blood glucose levels over the specified date range.  |
|  | <b>The Logbook Report</b> is a table of blood glucose, carbohydrate and insulin values for each day in the specified date range.  |

| Report  | What It Does  |
|---|---|
|  | <b>The Daily Statistics Report</b> provides an overview of blood glucose, carbohydrate and insulin data over the date range and displays it in a series of easy-to-read tables.   |
|  | <b>The Meal Event Averages Report</b> compares the before meal and after meal blood glucose levels for the morning, midday and evening times over the specified date range. This report also shows before and after meal averages, and insulin and carbohydrate intake for meals. |
|  | <b>The Meter Settings Report</b> shows current meter and insulin calculator settings and changes to the settings within the specified date range.   |

## Set up or Change Report Preferences


The FreeStyle Auto-Assist software allows you to set the following report preferences:

- Report set
- Time frame
- Glucose Targets (includes hypoglycaemia threshold)
- Auto-save options
- Print colour
- Quick print

**IMPORTANT:** Work with your health care professional to understand your report data.

**Note:** Your blood glucose targets and hypoglycaemia threshold preferences will only be used in the reports and will not change any meter settings.

**Note to health care professionals:** These preferences will be stored on your computer and will be used when creating reports from any meter.

| Step | Action   |
|------|--|
| 1    | Go to the <b>Reports</b> tab. If this is the first time you are creating reports, click  to be guided through the report preferences setup. |
| 2    | If you wish to change your report preferences, click <b>Report Preferences</b> on the left side of the screen. Use the submenus to change your report preferences.   |

## Create, View, Save and Print Reports

| Step | Action  |
|------|---|
| 1    | Go to the <b>Reports</b> tab. On the left side of the screen, click <b>Create Reports</b> .<br><b>Note:</b> You can change report settings from this screen by clicking <b>Edit</b> on the setting you wish to change. Click <b>Done</b> to save changes. These changes are not stored in Report Preferences.   |
| 2    | If you would like to preview the reports, click <b>View on Screen</b> .<br>Use the arrows to view the next/previous report page.<br><br>To save the report as a PDF, click <b>Save</b> .<br><b>Note:</b> The Adobe Acrobat Reader program must be installed on your computer to save files in Adobe Acrobat PDF format. Go to <b>www.Adobe.com</b> for instructions on downloading this program free over the Internet.<br><br>Click <b>Print</b> to print your selected reports. |

## Additional FreeStyle Auto-Assist Features

| Feature  | What It Does  | How To Access  |
|--|---|--|
| <b>First time Meter Setup</b>  | Sets your meter's language, date and time.                                  | If you have not yet set up your meter, plug it into your computer and click <b>Set up Meter</b> from the Welcome screen. |
| <b>Export Data</b>   | Exports meter data to a text file.  | From the menu bar at the top of the screen, click <b>File</b> . From the drop down, click <b>Export data</b> .           |
| <b>Update Software</b>   | Installs updates to your FreeStyle Auto-Assist software and meter.          | Your FreeStyle Auto-Assist software will alert you when updates are ready.   |
| <b>Backup Meter Files</b>  | Saves a backup file containing your current meter settings and preferences. | Go to the <b>Meter</b> tab. On the left side of the screen, click <b>Backups</b> . Click <b>Save backup file</b> .       |
| <b>Restore Meter Files</b>   | Replaces your current meter settings with settings from a backup file.      | Go to the <b>Meter</b> tab. On the left side of the screen, click <b>Backups</b> . Click <b>Restore Settings</b> .       |
| <p><b>IMPORTANT:</b> Make sure you choose the proper file to restore. If the incorrect file is chosen, the meter may be set with the wrong settings (such as insulin settings or blood glucose targets).</p> |   |  |

## Rapid-acting Insulin Calculator Setup

This feature can assist your patients with calculating their rapid-acting insulin doses based on meal and blood glucose level information.

**CAUTION:** This feature requires an understanding of the use of insulin. Misuse or misunderstanding of this feature and the suggested dose may lead to inappropriate insulin dosing. The calculator suggests doses for rapid-acting insulin only.

### How Does it Work?

#### ONE-time setup

Complete the setup to store your patient's individual insulin settings in the meter. *(Setup includes entering meal and correction insulin settings.)*

#### Use the calculator after a blood glucose test

The calculator will use the blood glucose result and the stored settings to calculate a suggested insulin dose based on:

Blood glucose  
correction (if needed)

+

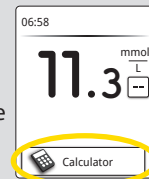
Meal/Carbohydrate  
intake

–

Active Insulin  
(if present)

=

Total  
suggested  
dose

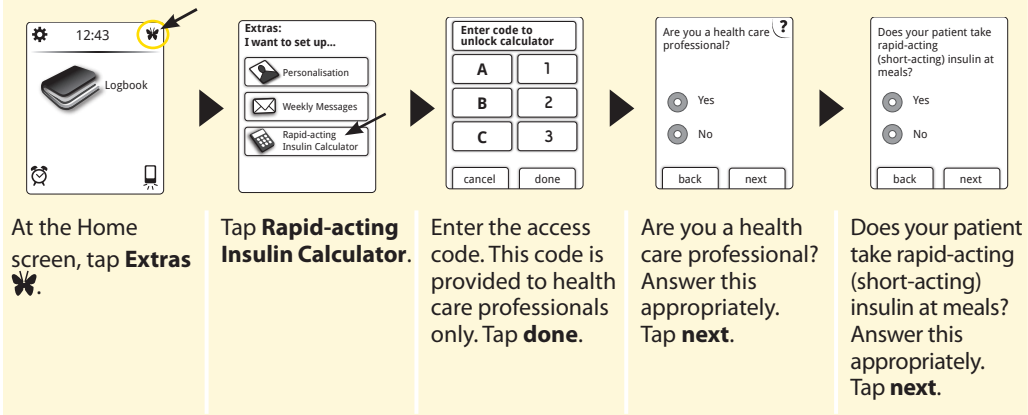


## Which Setup is Right for Your Patient?

| Setup Options   | Who is this for?  | What information is required?   |
|-----------------|---|---|
| <b>Easy</b>     | Patients who start with a fixed dose of rapid-acting insulin for meals.   | <ol style="list-style-type: none"> <li>Meal-time insulin doses: <ul style="list-style-type: none"> <li>Breakfast, lunch and dinner</li> </ul> </li> <li>Correction settings: <ul style="list-style-type: none"> <li>Correction target</li> <li>Correction factor - optional</li> </ul> </li> <li>Insulin duration - fixed at 4 hours</li> </ol>   |
| <b>Advanced</b> | Patients who count carbohydrates (in grams or carbohydrate portions) to adjust their rapid-acting insulin dose for meals. | <ol style="list-style-type: none"> <li>Meal-time insulin settings: <ul style="list-style-type: none"> <li>Grams of carbs or carbohydrate portions</li> <li>Carbohydrate ratio or carbohydrate portions ratio</li> </ul> </li> <li>Correction settings: <ul style="list-style-type: none"> <li>Correction target or target range</li> <li>Correction factor</li> </ul> </li> <li>Insulin duration</li> <li>Active Insulin</li> </ol> |

## Set up the Rapid-acting Insulin Calculator

**IMPORTANT:** If the time on the meter is wrong, this may lead to an incorrect suggested dose.

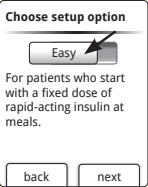
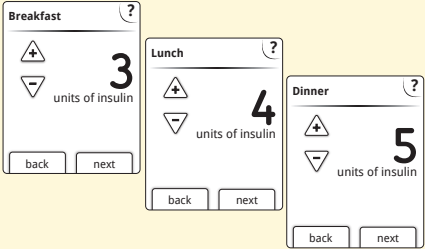


**Note:** While setting up the insulin calculator, tap the **?** Help button for more information.

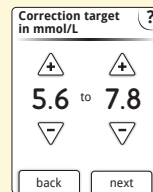


## Easy Setup

**IMPORTANT:** You must complete all the steps in the insulin calculator setup in order to use the insulin calculator.

| Step | Action   |
|------|--|
| 1    |  <p>To use the <b>Easy Setup</b>, tap <b>next</b>. For Advanced Setup, refer to the <i>Advanced Setup</i> section.</p>  |
| 2    |  <p>Enter the meal-time rapid-acting insulin doses. Tap <b>next</b> after each entry.</p> <p><b>Note:</b> If you require dosing in 0.5-unit increments, this can be changed through the FreeStyle Auto-Assist software application.</p> |

3

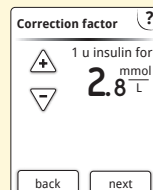


Enter the blood glucose correction target. Tap **next**.

This is the desired target range for blood glucose values before meals.

**Note:** If you want to set just one target value instead of a range, set both the low and high values to the same number.

4



Enter the correction factor (for example: if 1 unit of insulin lowers blood glucose 2.8 mmol/L, then the correction factor is 2.8). If the blood glucose value is outside the blood glucose target, the calculator will use the correction target and factor to calculate a correction dose. Tap **next**.

### Notes:

- If no correction insulin is taken, continue to tap the down arrow button past 1 to set **no correction insulin**. If you set **no correction insulin**, the calculator will **ONLY** include a meal dose, not a correction dose. Additionally, if **no correction insulin** is set, active insulin is not tracked or calculated.
- The average value of the target range is used to calculate the correction portion of the suggested dose.

5

Tap **done** to save the settings. When the patient uses the calculator, the meter will use the settings to suggest a rapid-acting insulin dose based on the meal selected and the latest blood glucose result.

To learn how to use the calculator, refer to the *Use Your Insulin Calculator with Easy Option* section.

### Notes about the Easy Option:

- In the Easy Option, the calculator estimates the amount of rapid-acting insulin still in the body and how much longer it may be active (if the correction factor is set to **no correction insulin**, active insulin is not calculated). The active insulin estimate is based on a 4-hour insulin duration calculated from the time and amount of the last logged rapid-acting insulin dose.
- Both meal and correction doses are included in the active insulin tracking.
- Insulin doses calculated 0-2 hours after a previously logged dose will only include a meal dose. A correction dose will not be included even if the blood glucose is outside the target. During this time period, the previous dose has not reached peak action and additional correction doses, referred to as 'insulin stacking', may result in hypoglycaemia. During this time period, active insulin will not be subtracted from any meal or carbohydrate dose.
- Insulin doses calculated 2-4 hours after a previously logged dose will have active insulin subtracted from the suggested dose.
- All previously injected insulin should be logged to ensure accurate active insulin tracking and calculations.

## Easy Option

This page can be used to record insulin calculator settings for your patient.

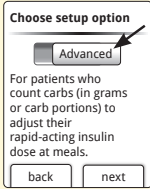
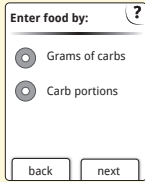
|   |   |  |  |
|---|---|--|--|
| <div>Breakfast Dose</div> <div><input type="text"/></div> <div>units of insulin</div> <div>0-50</div>   | <div>Lunch Dose</div> <div><input type="text"/></div> <div>units of insulin</div> <div>0-50</div> | <div>Dinner Dose</div> <div><input type="text"/></div> <div>units of insulin</div> <div>0-50</div> | ▶ This is the insulin required to cover your food.   |
| <div>Correction Target</div> <div> <input type="text"/> — <input type="text"/> </div> <div>mmol/L      mmol/L</div> <div>3.9-10.0      3.9-10.0</div> |   |  | ▶ This is the desired range for your before meal blood glucose.                            |
| <div>Correction Factor</div> <div>1 unit of insulin for</div> <div><input type="text"/></div> <div>mmol/L</div> <div>0.1-5.5 (or No Correction)</div> |   |  | ▶ This is the estimated amount your blood glucose will drop by taking one unit of insulin. |

Changes to these settings can only be made by your health care professional.



## Advanced Setup

**IMPORTANT:** You must complete all the steps in the insulin calculator setup in order to use the insulin calculator.

| Step | Action   |
|------|--|
| 1    |  <p>To use the <b>Advanced Setup</b>, tap the button to choose <b>Advanced</b>. Tap <b>next</b>.</p>  |
| 2    |  <p>Tap the selection to choose how meal/carbohydrate information will be entered. Tap <b>next</b>.</p> <p>If you selected <b>Grams of carbs</b>, go to Step 3.<br/>If you selected <b>Carb portions</b>, go to Step 4.</p> |

3

### Rapid-acting insulin dose suggestion is based on grams of carbs.

Use the arrow buttons to enter the carbohydrate ratio (1 unit of rapid-acting insulin for \_\_\_\_ grams of carbs).

Tap **next** when complete. Go to Step 5.

**Note:** If setting is based on time of day, tap **Optional: by time of day\***. Then tap **OK** after each entry to save.

4

### Rapid-acting insulin dose suggestion is based on carbohydrate portions.

Select the standard carbohydrate portion size (10, 12 or 15 grams of carbs) and tap **next**.

Use the arrow buttons to enter the carbohydrate portions ratio (the units of rapid-acting insulin per 1 carbohydrate portion). Tap **next** when complete.

**Note:** If setting is based on time of day, tap **Optional: by time of day\***. Then tap **OK** after each entry to save.

**Note:** If you require dosing in 0.5-unit increments, this can be changed through the FreeStyle Auto-Assist software application.

5

How do you want your patient to correct their glucose? To a single target or within a target range? Answer this appropriately. Tap **next**.

6

Enter the blood glucose correction target value or range.

This is the desired target value or range for blood glucose values before meals.

Tap **next** when complete.

**Note:** If setting is based on time of day, tap **Optional: by time of day\***. Then tap **OK** after each entry to save.

\* Time of day blocks cannot be adjusted. They correspond to the following times:

**Morning** 6:00 AM - 9:59 AM

**Evening** 4:00 PM - 9:59 PM (16:00 - 21:59)

**Midday** 10:00 AM - 3:59 PM (10:00 - 15:59)

**Night** 10:00 PM - 5:59 AM (22:00 - 5:59)

7

Enter the correction factor (for example: if 1 unit of insulin lowers blood glucose 2.8 mmol/L, then the correction factor is 2.8). If the blood glucose reading is outside the blood glucose target, the calculator will use the correction target and factor to calculate a correction dose.

Tap **next** when complete.

**Notes:**

- If setting is based on time of day, tap **Optional: by time of day\***. Then tap **OK** after each entry to save.
- The calculator corrects a blood glucose value to the single target or the average of the target range.
- The calculator will not provide a suggested dose that is estimated to drop the blood glucose level below the lower end of the target range or single target.

8


Enter the hours that rapid-acting insulin remains active in the body. Tap **next**.

**IMPORTANT:** In general, the insulin duration for rapid-acting insulin ranges from 3-5 hours, and can vary for each person.<sup>4</sup> The meter allows an insulin duration from 3-8 hours.

9

Do you want to turn on the Active Insulin feature? Tap your selection. Tap **next**.

**Notes:** If you choose to turn on this feature:


- Each time the calculator is used, the patient will be asked to confirm their last dose of rapid-acting insulin, and
- The home screen may show this symbol . This symbol shows an estimate of the amount of rapid-acting insulin still in the body and how much longer it may be active. To learn more about this symbol, refer to the *Use Your Insulin Calculator with Advanced Option* section.
- If you do not turn on the Active Insulin feature, active insulin is still included in the suggested dose calculation.

## 10

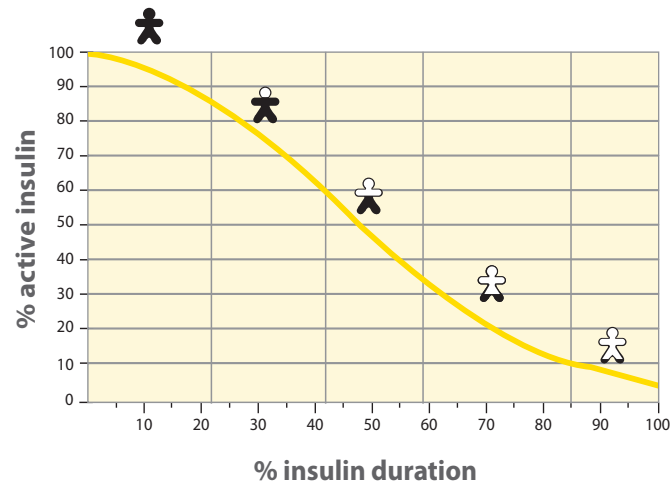
Tap **done** to save the settings. To learn how to use the calculator, refer to the *Use Your Insulin Calculator with Advanced Option* section.

### Notes about the Advanced Option:

- In the Advanced Option, the calculator estimates the amount of rapid-acting insulin still in the body and how much longer it may be active. The active insulin estimate is calculated from the set insulin duration and the time and amount of rapid acting insulin doses logged within the insulin duration.
- Both meal and correction doses are included in the active insulin tracking.
- Insulin doses calculated 0-2 hours after a previously logged dose will only include a meal dose. A correction dose will not be included even if the blood glucose is outside the target. During this time period, the previous dose has not reached peak action and additional correction doses, referred to as 'insulin stacking', may result in hypoglycaemia. During this time period, active insulin will not be subtracted from any meal or carbohydrate dose.
- Insulin doses calculated between 2 hours and the set insulin duration will have active insulin subtracted from the suggested dose (for example if insulin duration is set at 5 hours, active insulin will be subtracted from doses calculated between 2-5 hours).
- All previously injected insulin should be logged to ensure accurate active insulin tracking and calculations.

The graph below demonstrates how the insulin calculator estimates the amount of active insulin as a function of logged insulin dose and insulin duration over time. It shows the relationship between the  symbol and amount of active insulin.

### Active insulin curvilinear model



Adapted from Mudaliar et al. Diabetes Care, Volume 22(9), Sept 1999, pp 1501-1506

## Advanced Option

This page can be used to record insulin calculator settings for your patient.

Carbohydrate Ratio  
1 unit of insulin for

grams of carbs  
1-50

OR

1 Carbohydrate Portion

☐ 10 grams  
☐ 12 grams  
☐ 15 grams  
of carbs

Carbohydrate Portions Ratio  
For 1 carb portion take

units of insulin  
0.5-15



This is the number of grams of carbs that one unit of rapid-acting insulin will cover OR the number of units of rapid-acting insulin that will cover one carbohydrate portion. (Option to enter by time of day.)

Correction Target

mmol/L  
3.9-10.0

OR

Correction Target Range

 to 

mmol/L mmol/L  
3.9-10.0 3.9-10.0



This is the desired target or range for your before meal blood glucose. (Option to enter by time of day.)

Correction Factor  
1 unit of insulin for

mmol/L  
0.1-5.5



This is the estimated amount your blood glucose will drop by taking one unit of insulin. (Option to enter by time of day.)

Insulin Duration  
Insulin is active in the body for

hours:mins  
3-8



This is the amount of time that a dose of rapid-acting insulin remains active in your body.

Active Insulin feature?

☐ Yes ☐ No


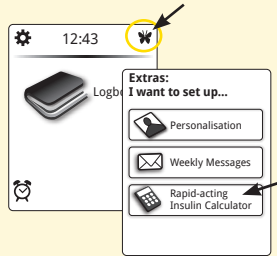
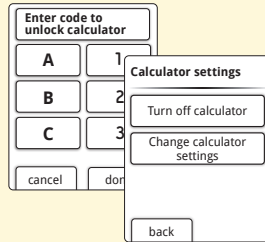


Refer to the *Use Your Insulin Calculator with Advanced Option* section for more information about this feature.

Changes to these settings can only be made by your health care professional.



## Change the Insulin Calculator Settings

| Step | Action  |
|------|---|
| 1    | <p>At the Home screen, tap <b>Extras</b> . Then tap <b>Rapid-acting Insulin Calculator</b>.</p>   |
| 2    | <p>Enter the access code provided only to health care professionals.</p> <p>Tap <b>Turn off calculator</b> to turn off the insulin calculator.</p> <p>OR</p> <p>Tap <b>Change calculator settings</b> to change the insulin calculator settings.</p> <p><b>Note:</b> If you turn off the insulin calculator, your patient will no longer see the calculator button after a test. You can turn the calculator back on by repeating the insulin calculator setup.</p>  |
| 3    | Refer to the <i>Easy</i> or <i>Advanced Setup</i> sections and follow the steps.  |



## Change Rapid-acting Insulin Dose Increments in FreeStyle Auto-Assist

Set the insulin dose increments to either 1.0 or 0.5 units for use with the Rapid-acting Insulin Calculator and Insulin Log features.

| Step | Action   |
|------|--|
| 1    | Go to the <b>Meter</b> tab. On the left side of the screen, click <b>Extras</b> .                |
| 2    | Click <b>Dose Increments</b> . Enter the access code provided only to health care professionals. |
| 3    | Click your choice, <b>1.0</b> unit or <b>0.5</b> unit.   |
| 4    | Click <b>Save to meter</b> .   |

## Meter Specifications

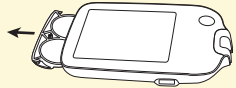

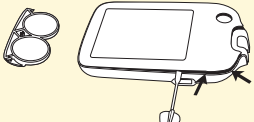
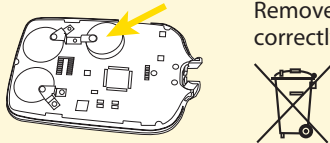
|                           |  |
|---------------------------|--|
| Altitude                  | Up to 3,048 metres (10,000 feet) above sea level                         |
| Assay method              | Coulometric electrochemical sensor                                       |
| Automatic shutoff         | Two minutes of inactivity  |
| Battery life              | Up to 3000 tests   |
| Calibration               | Plasma equivalent glucose values   |
| Haematocrit               | 15% to 65%   |
| Measurement unit          | mmol/L   |
| Meter storage temperature | -20 °C to 60 °C (-4 °F to 140 °F)  |
| Memory                    | Up to 165 days based on an average of 3 tests and 3 insulin logs per day |

|                                      |  |
|--------------------------------------|--|
| <b>Minimum Computer Requirements</b> | System must only be used with EN60950-1 rated computers.<br>Use a USB certified cable. |
| <b>Operating relative humidity</b>   | 5% to 90% (non-condensing)   |
| <b>Operating temperature</b>         | 4 °C to 40 °C (40 °F to 104 °F)  |
| <b>Power source</b>                  | Three CR 2032 3V lithium batteries, two of which are replaceable                       |
| <b>Result range</b>                  | 1.1 mmol/L to 27.8 mmol/L  |
| <b>Sample</b>                        | Fresh capillary and venous whole blood samples   |
| <b>Sample size</b>                   | 0.3 microlitre (300 nanolitres)  |
| <b>Size</b>                          | 6.0 cm (w) x 9.5 cm (l) x 1.5 cm (d)    2.4 in (w) x 3.8 in (l) x 0.6 in (d)           |
| <b>Weight</b>                        | 59.4 to 65.6 g (2.1 to 2.3 oz.) including batteries                                    |













| Insulin Calculator Specifications                         |   |                |
|---|---|----------------|
| Parameter   | Unit                                      | Range or Value |
| <b>Blood Glucose Target Range</b>                         | mmol/L                                    | 3.9 – 10.0     |
| <b>Single Blood Glucose Target</b>                        | mmol/L                                    | 3.9 – 10.0     |
| <b>Carbohydrate Insulin Ratio</b>                         | 1 unit per X grams of carbs               | 1 – 50         |
| <b>Carbohydrate Portions Ratio</b>                        | Units of insulin per carbohydrate portion | 0.5 – 15       |
| <b>Carbohydrate Portion Size</b>                          | Grams of carbs                            | 10, 12, 15     |
| <b>Meal-time Insulin Doses (breakfast, lunch, dinner)</b> | Units of insulin                          | 0 – 50         |
| <b>Correction Factor</b>                                  | 1 unit per X mmol/L                       | 0.1 – 5.5      |
| <b>Insulin Action Duration (Easy)</b>                     | Hours                                     | 4              |
| <b>Insulin Action Duration (Advanced)</b>                 | Hours                                     | 3 – 8          |
| <b>Dose Increments</b>                                    | Units of insulin                          | 0.5 or 1       |
| <b>Maximum Insulin Dose</b>                               | Units of insulin                          | 50             |

# Appendix A — End of Meter Life/ Backup Battery Removal

**Note:** Carry out this process only when you no longer intend to use the meter. The meter will no longer operate once opened to remove the backup battery.

| Step | Action  |
|------|---|
| 1    |  Remove battery door.  |
| 2    |  Insert small screwdriver blade between case above the USB port.                           |
| 3    |  Pry case open with screwdriver. Continue prying around the case until the case separates. |
| 4    |  Remove backup battery and dispose of battery and meter correctly.                         |

# Appendix B — Table of Symbols

|   |                              |   |   |
|---|------------------------------|---|---|
|  | Consult instructions for use |    | <i>In vitro</i> diagnostic medical device |
|  | Temperature limitation       |    | Catalogue number                          |
|  | Manufacturer                 |    | Recycle                                   |
|  | Batch code                   |    | Serial number                             |
|  | Do not reuse                 | <br>The batteries in this product should be removed and disposed of in accordance with local regulations for separate collection of spent batteries. |   |
|  | Caution                      |   |   |
|  | Use by                       |   |   |

## References:

- <sup>1</sup> "FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>
- <sup>2</sup> "CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010) <http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>
- <sup>3</sup> Definition and diagnosis of diabetes mellitus and intermediate hyperglycemia: report of a WHO/IDF consultation. World Health Organization, Geneva, Switzerland 2006.
- <sup>4</sup> Product Inserts: HumaLog®, NovoLog®, Apidra®
- <sup>5</sup> Diabetes Care. January 2010, vol. 33, no. Supplement 1, S11-S61.
- <sup>6</sup> Hirsch, I. (2005). Glycemic Variability: It's Not Just About A1C Anymore! Diabetes Technology and Therapeutics, 7 (5), 780-783.
- <sup>7</sup> Mayo Clinic Proceedings February 2007, vol. 82, no. 2, 229-236.
- <sup>8</sup> Pearson J, Bergenstal R. Fine-Tuning Control: Pattern Management Versus Supplementation: View 1: Pattern Management: an Essential Component of Effective Insulin Management. Diabetes Spectr. April 1, 2001; 14(2)75-78.